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| 10/616,884   | 07/10/2003  | Brian M. Hatcher     | 10856 (UFL0009US2)  | 2636             |
| 23413 7590 02/09/2009<br>CANTOR COLBURN, LLP<br>20 Church Street<br>22nd Floor<br>Hartford, CT 06103 |             |                      |                     |                  |
| EXAMINER<br>YOUNG, MICAH PAUL  |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1618   |             |                      |                     |                  |
| NOTIFICATION DATE  |             | DELIVERY MODE        |                     |                  |
| 02/09/2009   |             | ELECTRONIC           |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptopatentmail@cantorcolburn.com

# Office Action Summary

**Application No.**

10/616,884

**Applicant(s)**

HATCHER ET AL.

**Examiner**

MICAH-PAUL YOUNG

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

***Acknowledgement of Papers Received:*** Response dated 10/27/08

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-16, 21, 22, 24-31, and 34-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Silver et al (USPN 5,532,217 hereafter '217). The claims are drawn to a bioactive glass composite comprising biocompatible polymer and a bioactive glass.

The '217 patent teaches a biological composite comprising mineralized fibers, bioactive glass materials and biocompatible polymers (abstract). The bioactive glass comprises a calcium and phosphate molecule (col. 2, lin. 40-49). The biocompatible polymers include gelatin, lanolin or waxes (col. 2, lin. 50-53). The composite further comprises active agents such as hormones, enzymes and growth factors such as platelet-derived growth factors (col. 2, lin. 57-68). The material is used in bone repair therapies where the material is applied to treat bone defects (abstract, col. 2, lin. 5-16). The fibers have the diameter from less than 1 micron to 500 microns (claims). The composite is formed in a method that includes mixing the calcium with phosphate, carrier compounds and extrusion at a temperature of 37 degrees Celsius (example).

Regarding the composite at its ability to allow for the proliferation of stem cells, it is the position of the Examiner that these limitations are merely recitations of a future intended use. The claims recite that the "cells when seeded" will proliferate, meaning the composite is not yet

seeded and as such any proliferation would be an inherent feature of the composite. The composite of the instant claims comprises a bioactive glass materials and biocompatible polymers, while the '217 patent teaches an identical composite. Since a compound and its properties cannot be separated, and the composite of the '217 patent is identical to that of the instant claims, it is the position of the Examiner that the composite of the '217 patent would also proliferate any seeded cells.

Regarding the claim limitation drawn to the biocompatible polymer reacting with the bioactive glass compound, it is the position of the Examiner that such a limitation does not differentiate the claims over the prior art. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case the instant claims are defined by a composite comprising a biocompatible polymer and a bioactive glass. The '217 patent teaches a composite material comprising a biocompatible polymer (gelatin) and a bioglass (comprising a calcium and phosphate molecular species). The '217 patent meets the structural limitations of the claims and thus anticipates the instant claims.

For these reasons the claims are anticipated.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1618

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Silver et al (USPN 5,532,217 hereafter '217) in view of Shikinami (USPN 5,711,960 hereafter '960). The claims are drawn to a biocompatible composite comprising a biocompatible polymer, bioactive glass in the form of fibers that act as a scaffold.

As discussed above the '217 patent discloses a biocompatible composite comprising bioactive glass and a biocompatible polymer, the reference however is silent to the spacing of the fibers and their proximity to each other. The orderly arrangement of the fibers is common in the art as shown in the '960 patent.

The '960 patent discloses a biocompatible scaffold comprising a biocompatible polymer and bioactive glass on the surface of the fibers (abstract). The biocompatible polymers include polyethylene and poly-glycolic acid fibers (col. 10, lin. 50-61). Carriers for the scaffold include further biocompatible polymers such as cellulose gums and gelatin (col. 12, lin. 15-35). The bioactive glass is coated on the surface of the polymers (col. 18, lin. 29-42), and the bioactive glass polymers comprise calcium and phosphorous molecules (co. 17, lin. 45-col. 18, lin. 9).

From the figures it is clear the scaffold is orderly with the fibers being placed evenly apart in order to create a scaffold configuration (Figures). The fiber scaffold has a void fraction (porosity) of 20-90% (claim 2). Though silent to specific number the fibers are arranged in an orderly fashion and appear to touch leaving the space between them less than 25 microns (Figures). It would have been obvious to arrange the fibers of the '217 as described in the '960 patent since they both provide biocompatible scaffold materials with similar components.

Regarding the claim limitation drawn to the biocompatible polymer reacting with the bioactive glass compound, it is the position of the Examiner that such a limitation does not differentiate the claims over the prior art. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. See *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). In the instant case, the prior art discloses a structurally rally complete composite that is identical to that of the instant claims. As discussed above the '2317 patent discloses a composite material comprising gelatin and a bioglass compound.

With these things in mind it would have been obvious to arrange the fibers of the '217 patent as seen in the '960 patent in order to improve implant stability and compression properties

for implantation. It would have been obvious to apply the fiber arrangement with an expected result of a stable implantable composite useful in bone repair treatments.

***Response to Arguments***

Applicant's arguments filed 10/27/08 have been fully considered but they are not persuasive. Applicant argues that:

The Silver patent does not teach or suggest the biocompatible polymer being reacted with the bioactive glass limitation and thus does not anticipate the claims.

The combination of Silver and Shikinami does not obviate the claims since neither teaches or suggests the biocompatible polymer being reacted with the bioglass.

Regarding the first argument, it remains the position of the Examiner that the Silver patent anticipates the instant claims. Applicant argues that the "biocompatible polymer is reacted with the bioactive glass" limitation is ignored, however as discussed above the limitation is regarded as a product-by-process limitation and as such does not distinguish the claims over the prior art. Specifically the limitation requires a processing step of "reacting" the two composite materials, yet the claim is drawn to a product. The Silver patent teaches a structurally identical product comprising a bioglass and a biocompatible polymer. The bioglass comprises a calcium and phosphorus molecular combination identical to that of the instant claims. The biocompatible polymer is identical to those recited in claim 44. As such the Silver patent teaches a composite material comprising an identical biocompatible polymer and a bioglass material. For these reasons the claims remain anticipated.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the as discussed above the Silver patent discloses a composite material, however the patent is silent to the specific spacing of the fibers. The Shikinami patent is merely used to establish the level of skill in the art regarding scaffolding fibers. The Silver patent discloses a composite comprises fibers in a supporting scaffolding configuration, yet is silent to individual spacing. The Shikinami patent provides a scaffold product where the fibers are spaced less than 25 microns apart. Applicant argues that the patent teach divergent products, however the patents are combined for different purposes. The Silver patent discloses a composite material comprises fibers, and the Shikinami patent discloses how to space the fibers in order to provide a stable carrier scaffold material. The combination of teachings and suggestions would have been obvious since both patents solve the same problem of drug delivery using biocompatible scaffoldings. For these reason the claims remain obviated.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,



however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/  
Examiner, Art Unit 1618